



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1646-N]

Medicare Program; Public Meeting on July 18, 2016 regarding New and Reconsidered Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2017

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting to receive comments and recommendations (including accompanying data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for new or substantially revised Healthcare Common Procedure Coding System (HCPCS) codes being considered for Medicare payment under the clinical laboratory fee schedule (CLFS) for calendar year (CY) 2017. This meeting also provides a forum for those who submitted certain reconsideration requests regarding final determinations made last year on new test codes and for the public to provide comment on the requests.

DATES: Meeting Date: The public meeting is scheduled for Monday, July 18, 2016 from 9:00 a.m. to 3:00 p.m., Eastern Daylight Savings Time (E.D.T.)

Deadline for Registration of Presenters and Submission of Presentations: All presenters for the public meeting must register and submit their presentations electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov by July 1, 2016 E.D.T.

Deadline for Submitting Requests for Special Accommodations: Requests for special accommodations must be received no later than 5:00 p.m. on July 1, 2016 E.D.T.

Deadline for Submission of Written Comments: We intend to publish our proposed determinations for new test codes and our preliminary determinations for reconsidered codes (as described below in section II. Format) for CY 2017 by early September 2016. Interested parties may submit written comments on these determinations by early October, 2016, to the address specified in the “**ADDRESSES**” section of this notice or electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov (the specific date for the publication of these determinations on the CMS web site, as well as the deadline for submitting comments regarding these determinations will be published on the CMS web site).

ADDRESSES: The public meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

FOR FURTHER INFORMATION CONTACT:

Glenn McGuirk, (410) 786-5723.

SUPPLEMENTARY INFORMATION:

I. Background

Section 531(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish procedures for coding and payment determinations for new clinical diagnostic laboratory tests under Part B of title XVIII of the Social Security Act (the Act) that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for International Classification of Diseases (ICD-9-CM). The procedures and public meeting announced in this notice for new

tests are in accordance with the procedures published on November 23, 2001 in the **Federal Register** (66 FR 58743) to implement section 531(b) of BIPA.

Section 942(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) added section 1833(h)(8) of the Act. Section 1833(h)(8)(A) of the Act requires the Secretary to establish by regulation procedures for determining the basis for, and amount of, payment for any clinical diagnostic laboratory test with respect to which a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code is assigned on or after January 1, 2005 (hereinafter referred to as “new tests”). A code is considered to be substantially revised if there is a substantive change to the definition of the test or procedure to which the code applies (such as, a new analyte or a new methodology for measuring an existing analyte-specific test). (See section 1833(h)(8)(E)(ii) of the Act).

Section 1833(h)(8)(B) of the Act sets forth the process for determining the basis for, and the amount of, payment for new tests. Pertinent to this notice, section 1833(h)(8)(B)(i) and (ii) of the Act requires the Secretary to make available to the public a list that includes any such test for which establishment of a payment amount is being considered for a year and, on the same day that the list is made available, causes to have published a notice in the **Federal Register** of a meeting to receive comments and recommendations (including accompanying data on which recommendations are based) from the public on the appropriate basis for establishing payment amounts for the tests on such list. This list of codes for which the establishment of a payment amount under the clinical laboratory fee schedule (CLFS) is being considered for calendar year (CY) 2017 is posted on the CMS web site at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. Section 1833(h)(8)(B)(iii) of the Act requires that we convene the public meeting not less than 30 days

after publication of the notice in the **Federal Register**. These requirements are codified at 42 CFR part 414, subpart G.

Two bases of payment are used to establish payment amounts for new tests. The first basis, called “crosswalking,” is used when a new test code is determined to be comparable to an existing test code, multiple existing test codes, or a portion of an existing test code. The new test code is assigned the local fee schedule amounts and the national limitation amount of the existing test. Payment for the new test is made at the lesser of the billed amount, the local fee schedule amount, or the national limitation amount. (See §414.508(a).)

The second basis called “gapfilling,” is used when no comparable existing test is available. When using this method, instructions are provided to each Part A and Part B Medicare Administrative Contractor (MAC) to determine a payment amount for its Part B geographic area for use in the first year. The contractor-specific amounts are established for the new test code using the following sources of information, if available: (1) charges for the test and routine discounts to charges; (2) resources required to perform the test; (3) payment amounts determined by other payers; and (4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. (See §414.508(b) and §414.509 for more information regarding the gapfilling process.)

Under section 1833(h)(8)(B)(iv) of the Act, the Secretary, taking into account the comments and recommendations (and accompanying data) received at the public meeting, develops and makes available to the public a list of proposed determinations with respect to the appropriate basis for establishing a payment amount for each code, an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on the proposed determinations. Under section 1833(h)(8)(B)(v) of the Act,

taking into account the comments received on the proposed determinations during the public comment period, the Secretary then develops and makes available to the public a list of final determinations of final payment amounts for new test codes along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

After the final determinations have been posted on the CMS web site, the public may request reconsideration of the basis and amount of payment for a new test as set forth in §414.509. Pertinent to this notice, those requesting that CMS reconsider the basis for payment or, for crosswalking, reconsider the payment amount as set forth in §414.509(a) and (b)(1) may present their reconsideration requests at the following year's public meeting provided that the requestor made the request to present at the public meeting in the written reconsideration request. For purposes of this notice, we refer to these codes as the "reconsidered codes." The public may comment on the reconsideration requests. (See the November 27, 2007 CY 2008 Physician Fee Schedule final rule with comment period (72 FR 66275 through 66280) for more information on these procedures.)

II. Format

We are following our usual process, including an annual public meeting to determine the appropriate basis and payment amount for new and reconsidered test codes under the CLFS for CY 2017.

This meeting is open to the public. The on-site check-in for visitors will be held from 8:30 a.m. to 9:00 a.m., followed by opening remarks. Registered persons from the public may discuss and make recommendations for specific new and reconsidered test codes for the CY 2017 CLFS.

We note that the July 2016 Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel meeting and the laboratory public meeting will be a joint meeting this year, on July 18, 2016. The announcement for the CDLT Advisory Panel meeting will be included in a separate **Federal Register** notice.

Because of time constraints, presentations must be brief, lasting no longer than 10 minutes, and must be accompanied by three written copies. In addition, presenters should make copies available for approximately 50 meeting participants, since CMS will not be providing additional copies. Written presentations must be electronically submitted to CMS on or before July 1, 2016. Presentation slots will be assigned on a first-come, first-served basis. In the event that there is not enough time for presentations by everyone who is interested in presenting, CMS will gladly accept written presentations from those who were unable to present due to time constraints. Presentations should be sent via email to Glenn McGuirk, at Glenn.McGuirk@cms.hhs.gov. For reconsidered and new test codes, presenters should address all of the following 5 items:

- (1) Reconsidered or new test codes and descriptor.
- (2) Test purpose and method.
- (3) Costs.
- (4) Charges.
- (5) Recommendation with rationale for one of the two bases (crosswalking or gapfilling) for determining payment for reconsidered and new tests.

Additionally, the presenters should provide the data on which their recommendations are based. Written presentations from the public meeting will be available upon request, via email to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov. Presentations regarding reconsidered and new

test codes that do not address the above five items for presenters may be considered incomplete and may not be considered by CMS when making a determination. However, we may request missing information following the meeting to prevent a recommendation from being considered incomplete.

Taking into account the comments and recommendations (and accompanying data) received at the public meeting, we intend to post our proposed determinations with respect to the appropriate basis for establishing a payment amount for each new test code and our preliminary determinations with respect to the reconsidered codes along with an explanation of the reasons for each determination, the data on which the determinations are based, and a request for public written comments on these determinations on the CMS web site by early September 2016. This web site can be accessed at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. We also will include a summary of all comments received by August 8, 2016 (15 business days after the meeting). Interested parties may submit written comments on the proposed determinations for new test codes or the preliminary determinations for reconsidered codes by early October, 2016, to the address specified in the “**ADDRESSES**” section of this notice or electronically to Glenn McGuirk at Glenn.McGuirk@cms.hhs.gov (the specific date for the publication of the determinations on the CMS web site, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS web site). Final determinations for new test codes to be included for payment on the CLFS for CY 2017 and reconsidered codes will be posted on the CMS web site in November 2016, along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public. The final determinations with respect to reconsidered codes are not

subject to further reconsideration. With respect to the final determinations for new test codes, the public may request reconsideration of the basis and amount of payment as set forth in §414.509.

III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the public meeting registration. Beginning June 6, 2016, registration may be completed on-line at the following web site: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>. All the following information must be submitted when registering:

- Name.
- Company name.
- Address.
- Telephone numbers.
- E-mail addresses.

When registering, individuals who want to make a presentation must also specify, which new test codes they will be presenting comments. A confirmation will be sent upon receipt of the registration. Individuals must register by the date specified in the “**DATES**” section of this notice.

IV. Security, Building, and Parking Guidelines

The meeting will be held in a Federal government building; therefore, Federal security measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. It is suggested that you arrive at the CMS facility between 8:15 a.m. and 8:30 a.m., so that you will be able to arrive promptly at the meeting by 9:00 a.m. Individuals who are

not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 8:15 a.m. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building.

We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

V. Special Accommodations

Individuals attending the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should provide that information upon registering for the meeting. The deadline for registration is listed in the “**DATES**” section of this notice.

Dated: April 11, 2016

Andrew M. Slavitt,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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